Research Record Retention

Subject Payments for Studies Involving Minors

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Research Record Retention
Research studies generate a lot of paper.

- Protocols
- Investigator’s brochures
- Regulatory documents and logs
- Consents
- Source documents
- CRF binders
- Promotional materials
Research record retention is governed by multiple entities.
DHHS rules can be found at 45 CFR 46.115(b)

*Institutions* must keep records of IRB activity and “records relating to research that is conducted” for at least 3 years after completion.

Institutions can delegate to investigators.
Form A
HUMAN USE RESEARCH
SIGNATURE ASSURANCE SHEET

Study Title:

Principal Investigator's Assurance Statement:
I understand my institution's policies concerning research involving human subjects and the IRB's policies for protection of human subjects. I will:

- protect the rights, safety and welfare of the subjects involved in this research;
- ensure research is conducted in an ethical manner and in accordance with all laws, regulations, or policies applicable to the protection for human research subjects and requirements and determinations of the IRB;
- personally conduct or oversee those who conduct this research;
- supervise study personnel to whom tasks are delegated. Ensure that study personnel: 1) are qualified by training and experience and licensure to perform study-related tasks that have been delegated to them; 2) have an adequate understanding of the research; and 3) follow the IRB-approved protocol, including the recruitment and consent procedures described in the protocol summary;
- ensure that study subjects are provided with: 1) reasonable medical care for any adverse events, including clinically significant laboratory values, related to the research; 2) a qualified contact to answer questions or provide care during the conduct of the research; and 3) the study plan is followed, such as inclusion/exclusion criteria, safety assessments, safety monitoring and reporting of unanticipated problems, and procedures to protect privacy of subjects and confidentiality of identifiable data, in order to minimize risks to subjects;

- obtain, document, and maintain records of informed consent from each subject or when approved by the IRB the subject's legally authorized representative using the consent document(s) approved by the IRB;
- conduct the research in accordance with the protocol approved by the IRB;
- initiate changes in the research, including the approved consent form(s), only after IRB approval, except where necessary to eliminate apparent immediate hazards to subjects;
- report promptly to the IRB and to the subjects, any significant findings or new information that becomes known in the course of the research that might change the risk of or justification for the research or may otherwise affect the willingness of subjects to participate or to continue to participate in the research;
- report promptly to the IRB, any unanticipated problems involving risks to subjects or others in research;
- operate within the parameters that have been defined in the authorization portion of the consent regarding Protected Health Information (PHI);
- comply with all applicable FDA regulations, including the Good Clinical Practices Guidelines, and fulfill all investigator responsibilities (or investigator-sponsor responsibilities, where appropriate), including those described at 21 CFR 312 & 812;
- control drugs, biological products, and devices used for research purposes;
- submit a progress report for continuing review prior to expiration of IRB approval in accordance with UTHSCSA Policy;
- halt all research activities should IRB approval lapse, until the IRB re-approves the research or until special permission is obtained from the IRB to continue previously enrolled subjects if determined to be in their best interests to do so;
- promptly submit a final report when the research has been completed or is being closed out prior to completion.

- maintain adequate and accurate research records in accordance with institutional and, when applicable, the sponsor or FDA requirements.
The FDA rules are at 21 CFR 312.62(c) and 21 CFR 812.140(a)

- Investigational drugs
- Investigational devices
The FDA rules require the investigator to retain many documents

- Research Records
- Case Histories
  - Case Report Forms
  - Supporting Data
- Safety Reports
- Final Reports
- Financial Disclosure Reports
- Records Of Drug Disposition
- Case histories and exposure to the device
- Correspondence with another investigator, sponsor, monitor, or FDA
- Records of receipt, use or disposition of device
- Protocol
- Deviations from the protocol
FDA retention guidelines may not start with the end of the study

For INDs (drugs): 2 years after marketing application approval OR 2 years after disapproval or the decision not to file

For IDEs (devices): 2 years after end of study OR 2 years after records are no longer needed to support an FDA submission
Sponsor rules can be longer than regulatory requirements

Sponsor requirements can sometimes be found in trial documents:

Clinical trial agreement
Protocol
Contact your sponsor
UT HSC rules are listed on the library website

http://library.uthscsa.edu/rrs/recordrs.php

Institutional rules depend on the document

Timeframes are often longer than the federal requirements
Grant records that include clinical trials/drug studies

Research data and documentation
Federal and non-federal grants and sponsored agreements
3 years after completion of the study and drug approval
Human research protocols

6 years after inactivation of the protocol
Longer if associated grant records are being retained
Signed consent forms

Adults:
10 years after last contact with subject

Minors:
10 years OR until age 21, whichever is longer
Research data and participant records

If they are not part of the medical record, as long as they are “administratively valuable”
Medical records are maintained by the clinics for longer periods

10 years past the date the patient was last treated for adults

Age 18 OR 10 years past last treatment for minors
Don’t forget HIPAA!

If your data is PHI generated by or received by a Covered Entity, it needs to be kept 6 years to satisfy HIPAA requirements.

This may apply to treatment studies.
Always keep research documents as prescribed by the longest applicable rule

Sponsor requirements are often the longest—*always* check with them before destroying anything.

If unsponsored, UT Health guidelines may be the longest.

Consider regularly cleaning out documents that are no longer needed.
Subject Payments for Studies Involving Minors
Payments in studies involving minors have unique issues
Four categories of payments to participants
Reimbursement is payment to cover direct expenses
Compensation is payment to offset the time and inconvenience of participation.
Appreciation bonuses are given after participation as a thank-you.
Incentive is payment beyond expenses to encourage enrollment
Which payment types minimize undue influence?
Age needs to be considered when setting compensation rates
Always consider the possibility of undue influence when minors are involved in paid research

Ensure that payments are suitable and go to the person bearing the burden of participation
The IRB will evaluate research plans on a case-by-case basis
Research Concierge Service

We offer regulatory guidance and assistance for research staff at no charge!

Representatives from our offices are eager to assist you.

- **IRB**
  - UTHSA IRB Human Studies

- **IACUC**
  - Animal Studies & ORCA

- **OCR**
  - External IRB Human Studies, Personnel & Training

- **CTO**
  - Clinical Trials, Budget & Subject Payment

- **CIRD**
  - Clinical Informatics Research Division

Available on 2nd Tuesday only

- **VA**
  - VA R&D for Human Studies

Available on 2nd Wednesday Only

- **UHS**
  - UHS Research Dept.

Tuesday, February 5, 2019, 1pm – 4pm
Wednesday, February 13, 2019, 9am – 12pm
Wednesday, February 27, 2019, 9am – 12pm

Location: Library – 2nd Floor Computer Classroom – 2.011

Starting February 15, 2018, clinical trials will be reviewed and cleared by the Clinical Trials Office (CTO) before the research application is submitted to the IRB or the OCR.

Learn more about this new clinical trial submission process! [http://research.uthscsa.edu/cto/index.shtml](http://research.uthscsa.edu/cto/index.shtml)

The Research Protection Programs Offices are resources of the Office of the Vice President for Research